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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/772,271

02/06/2004

Takayuki Asahara

US-107

4145

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7590

08/08/2006

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EXAMINER

GANGLE, BRIAN J

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 08/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/772,271	Applicant(s) ASAHARA ET AL.	
	Examiner Brian J. Gangle	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 06 February 2004.
- 2a) ☐ This action is FINAL.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-9 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-3, drawn to DNA that has the sequence of SEQ ID NO:X, or that encodes a protein with the sequence of SEQ ID NO:X, classified in class 536, subclass 23.1.
- II. Claims 4-5, drawn to a recombinant methanol-utilizing bacterium, wherein said bacterium has an improved ability to produce a polysaccharide, classified in class 435, subclass 252.1.
- III. Claim 6, drawn to a method for producing a polysaccharide, utilizing a recombinant methanol-utilizing bacterium, wherein said bacterium has an improved ability to produce a polysaccharide, classified in class 435, subclass 101.
- IV. Claims 7-8, drawn to a recombinant methanol-utilizing bacterium, wherein said bacterium has an ability to reduce production of a polysaccharide, classified in class 435, subclass 252.1.
- V. Claim 9, drawn to a method for producing a target substance other than polysaccharide, utilizing a recombinant methanol-utilizing bacterium, wherein said bacterium has an ability to reduce production of a polysaccharide. This invention cannot be classified without knowing the target substance.

### **Sequence Election Requirement Applicable to All Groups**

In addition, each Group detailed above reads on patentably distinct SEQ ID NOs. Each sequence is patentably distinct because they are drawn to sequences with differing biochemical and immunological properties and a further restriction is applied to each Group. Applicant must further elect a single SEQ ID NO.

**Applicant is advised that examination will be restricted to only the elected microbial species and gene and should not be construed as a species election.**

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The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as products. The claims of Invention I are drawn to DNA while the claims of Invention II are drawn to a bacterium with an improved ability to produce a polysaccharide. The inventions are patentably distinct products because they are made by different methods and because they are physically and functionally distinct chemical entities with no common core structure.

The products of Invention I are separate and distinct from the methods of Invention III, wherein the products of Invention I may neither be made by nor used in the methods of Invention III. In the instant case, Invention III is drawn to a method of producing a polysaccharide using a methanol-utilizing bacterium, while Invention I is drawn to DNA.

Inventions I and IV are related as products. The claims of Invention I are drawn to DNA while the claims of Invention IV are drawn to a bacterium with a reduced ability to produce a polysaccharide. The inventions are patentably distinct products because they are made by different methods and because they are physically and functionally distinct chemical entities with no common core structure.

The products of Invention I are separate and distinct from the methods of Invention V, wherein the products of Invention I may neither be made by nor used in the methods of Invention V. In the instant case, Invention V is drawn to a method of producing a target substance, other than polysaccharide, using a methanol-utilizing bacterium, while Invention I is drawn to DNA.

Inventions II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the bacterium of Invention II can be used to raise antibodies.

Inventions II and IV are related as products. The claims of Invention II are drawn to a methanol-utilizing bacterium with an improved ability to produce a polysaccharide while the claims of Invention IV are drawn to a bacterium with a reduced ability to produce a polysaccharide. The inventions are patentably distinct products because they are made by different methods and because they are physically and functionally distinct chemical entities with no common core structure.

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The products of Invention II are separate and distinct from the methods of Invention V, wherein the products of Invention I may neither be made by nor used in the methods of Invention V. In the instant case, Invention V is drawn to a method of producing a target substance, other than polysaccharide, using a methanol-utilizing bacterium, while Invention II is drawn to a bacterium with an enhanced ability to produce polysaccharide.

The products of Invention IV are separate and distinct from the methods of Invention III, wherein the products of Invention IV may neither be made by nor used in the methods of Invention III. In the instant case, Invention III is drawn to a method of producing a polysaccharide using a methanol-utilizing bacterium, while Invention IV is drawn to methanol-utilizing bacterium that has an ability to reduce production of a polysaccharide.

Inventions III and IV are related as methods. The methods are distinct from one another because they have different goals as evidenced by the preamble (producing a polysaccharide, producing a target substance other than polysaccharide), utilize different reagents (bacterium with an enhanced ability to produce polysaccharide, bacterium with reduced ability to produce polysaccharide) and have different final outcomes. Consequently, each method is distinct from the other.

Inventions IV and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the bacterium of Invention IV can be used to raise antibodies.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

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Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

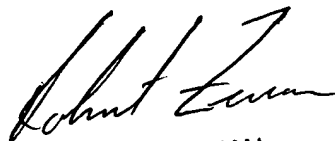
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Gangle whose telephone number is (571) 272-1181. The examiner can normally be reached on M-F 8-4:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Brian Gangle  
7/19/2006

  
ROBERT A. ZEMAN  
PRIMARY EXAMINER